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Filed : October 28, 2003

## REMARKS

Claim 1 has been amended to more clearly state what the Applicants consider as their invention and to recite the proviso that the silicone composition is not produced from a precursor comprising diisocyanate. Support for these amendments may be found in the specification, for example, in paragraphs 6, 7, and 189. New Claims 135-139 have been added. Support for Claims 135-137 may be found in the specification, for example, in paragraph 230. Support for Claim 138 may be found in the specification, for example, in paragraph 10. Support for Claim 139 may be found in the specification, for example, in paragraph 229. Claims 27-134 have been canceled. Claims 1-26 and 135-138 are pending in the application. The Applicants have carefully considered all of the Examiner's rejections but respectfully submit that the claims are allowable for at least the following reasons.

### Restriction Requirement

The application was restricted to one of four groups of inventions. The Applicants hereby affirm their provisional election of Group I, Claims 1-26, without traverse. Claims 27-134 are herein canceled without prejudice to pursuing the subject matter of the claims in a continuation, divisional, or continuation-in-part application.

### Rejections under § 102

The Examiner rejected Claims 1-12 and 17-26 under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,528,584 (Kennedy). "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." M.P.E.P. § 2131 (quoting *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 621, 631 (Fed. Cir. 1987)). The Examiner argued that Kennedy met the "controls transport of an analyte" limitation of Claim 1 by disclosing that its membrane was permeable to water, hydrocarbons, and oxygen. However, Kennedy does not disclose that its membrane material has the necessary properties to control transport of an analyte through the membrane. Instead, Kennedy teaches that its membranes swell in water and in hexane, which Kennedy asserts is evidence of water and hexane permeability. Kennedy, column 13, lines 10-40. Such permeability does not imply that the material will *control* the transport (e.g., diffusion resistance) of an analyte (e.g., glucose) through the membrane. *See* MPEP § 2112(IV) ("The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to

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establish the inherency of that result or characteristic...In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art.") Accordingly, the Applicants respectfully submit that Claims 1-12 and 17-26 are not anticipated by Kennedy.

Furthermore, new Claim 135 recites that the claimed silicon composition has an oxygen-to-analyte permeability ratio such that oxygen is provided to an immobilized enzyme in a non-rate-limiting excess for an enzyme-catalyzed reaction between oxygen and the analyte. Kennedy does not disclose that its material has these properties and the Examiner has not provided a basis in fact and/or technical reasoning to support a determination that the material has these properties. Similarly, new Claim 136 recites that the oxygen-to-analyte permeability ratio of the composition is approximately 200:1. Kennedy does not teach that its material has this property. As such, Kennedy does not anticipate New Claims 135-136 for these additional reasons.

The Examiner also rejected Claims 1-26 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,777,060 (Van Antwerp). Van Antwerp only discloses membranes formed by the reaction mixture of diisocyanate, a hydrophilic polymer, and a silicone polymer. Van Antwerp, column 5, lines 43-58. Claim 1 now contains a proviso reciting that the claimed silicone composition is not produced from a precursor comprising diisocyanate. As such, the Applicants respectfully submit that Claims 1-26 are not anticipated by Van Antwerp.

The Examiner also rejected Claims 1-5, 7, 8, 10, 11, and 17-19 under 35 U.S.C. § 102(e) as being anticipated by U.S. Application Publication No. 2003-0059631 (Al-Lamee). Al-Lamee discloses the organopolysiloxane coating poly-[dimethylsiloxane-co-methyl-(3-hydroxypropyl)siloxane]-graft-poly(ethylene glycol) [3-(trimethylammonio) propyl chloride] ether. The Examiner did not indicate how this disclosure meets the Claim 1 limitation of controlling transport of an analyte through the membrane. In fact, Al-Lamee does not disclose that its coatings have the necessary properties to control transport of an analyte therethrough. As such, the Applicants respectfully submit that Claims 1-5, 7, 8, 10, 11, and 17-19 are not anticipated by Al-Lamee.

Furthermore, as discussed above with reference to Kennedy, new Claims 135 and 136 recite further limitations regarding the oxygen-to-analyte permeability ratio of the claimed

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silicone composition. Al-Lamee does not disclose that its material has these properties. Accordingly, Al-Lamee does not anticipate new Claims 135-136 for these additional reasons.

Finally, the Examiner rejected Claims 1-12, 17, and 19-26 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 4,260,725 (Keogh et al.). Keogh discloses that its polysiloxane polymers with hydrophilic sidechains absorb water and transport oxygen. However, as discussed above with respect to Kennedy, water absorption does not imply that the material will control the transport (e.g., diffusion resistance) of an analyte (e.g., glucose) through the membrane. Keogh does not disclose that its material has the necessary properties to control transport of an analyte therethrough. Accordingly, the Applicants respectfully submit that Claims 1-12, 17, and 19-26 are not anticipated by Keogh. Furthermore, Keogh does not disclose that its material has the oxygen-to-analyte permeability properties claimed in new Claims 135-136.

Rejections under § 103

The Examiner rejected Claims 13 and 15 under 35 U.S.C. § 103(a) as being obvious over Al-Lamee. A *prima facie* case of obviousness requires that all of the claim limitations are taught or suggested by the prior art. *See* M.P.E.P. § 2143.03. As discussed above, Al-Lamee does not disclose all of the limitations of independent Claim 1. Accordingly, the Applicants respectfully submit that Al-Lamee does not teach or suggest all of the limitations of dependent Claims 13 and 15.

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### CONCLUSION

The Applicants respectfully submit that, by the foregoing amendments and remarks, they have overcome all of the rejections and request a timely issuance of a Notice of Allowance.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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Dated: 3/6/06

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